

Appl. No.: 09/923,626

Group Art Unit: 1616

Applicants' Response to the Office Action Dated June 29, 2004

### REMARKS

Claims 1-19 are currently pending in the present application.

In the Office Action, the Examiner acknowledges receipt of Applicants' Brief on Appeal filed on March 11, 2004. The Examiner has withdrawn the previous rejection of claims 1-19 under 35 U.S.C. §103(a), as being unpatentable over Fizet (abstract of EP 610742, U.S. Pat. No. 5,487,817). The Examiner has withdrawn the finality of the Office Action dated April 9, 2003 (Paper No. 10), and has reopened prosecution of the instant application, setting forth two new rejections.

In the Office Action, the Examiner provisionally rejects claims 1-19 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-32 of copending application number 09/923,629 ("the copending application"). The Examiner contends that "[t]he claims in this application are very similar to the claims in Application No. 09/923,629[, and that n]o specific difference was found which could make these two applicants patentably distinct from one another." (*See*, the Office Action, p. 3).

Applicants respectfully traverse the Examiner's rejection and the contentions set forth in support thereof for the following reasons. The instant application and the copending application both claim processes for producing sterols. The processes for producing sterols, as claimed in the instant application, and the processes for producing sterols, as claimed in the copending application, both include multiple transesterifications. However, the processes claimed in the instant application require "providing an oil distillation residue" and transesterifying components in the oil distillation residue. In contrast, the processes claimed in the copending application require "providing a fatty acid production-residue" which contains free fatty acids and "removing the free fatty acids", followed by transesterification. Thus, while both the processes claimed in the instant application and the processes claimed in the copending application are both directed to the production of sterols, the claims differ in the starting materials employed and the treatment of those starting materials prior to the initial transesterification.

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Applicants respectfully submit that the claims of the instant application are patentably distinct from the claims of the copending application. Claims directed to the transesterification of a fatty acid production-residue, said residue having had the free fatty acids contained therein removed prior to transesterification, does not teach or suggest the transesterification of an oil distillation residue.

Accordingly, reconsideration and withdrawal of the provisional rejection under the judicially created doctrine of obviousness-type double patenting are requested.

In the Office Action, the Examiner rejects claims 1-19 under 35 U.S.C. §103(a), as being unpatentable over U.S. Pat. No. 5,703,252 of Hunt, *et al.* (hereinafter referred to as "Hunt '252"), in combination with U.S. Pat. No. 5,670,669 of Hunt, *et al.* (hereinafter referred to as "Hunt '669"). Specifically, the Examiner contends that Hunt '252 discloses "a process for the recovery of tocopherols from a starting material containing fatty and sterol compounds . . . ." (See, the Office Action, p. 3). The Examiner also contends that Hunt '252 discloses (a) the esterification of free fatty acids with a lower alcohol; (b) the transesterification of fatty acid glyceride esters with a lower alcohol in the presence of a zinc catalyst; (c) the removal of excess lower alcohol, catalyst, fatty acid alkyl esters and glycerol; and (d) complete conversion of sterol esters to free sterols by reaction with a lower alcohol in the presence of an alkoxide catalyst. (See, *id.* at pp. 3-4). The Examiner notes that Hunt '669 discloses a similar process. The Examiner also notes that the transesterifications disclosed in the Hunt references are conducted at temperatures of from 150°C to 240°C for periods of from about 1 to 3 hours under pressure.

On these bases, the Examiner concludes that the subject matter of the instant claims would have been obvious within the meaning of 35 U.S.C. §103(a).

Applicants strenuously traverse the Examiner's rejection, along with her contentions and arguments in support thereof for the following reasons.

It is well-settled that in order for an Examiner to establish a *prima facie* case of obviousness, and thus shift the burden of proving non-obviousness onto Applicants, each of the following three criteria must be satisfied: (1) there must be some suggestion or motivation to modify or combine the references as suggested by the Examiner (it is not sufficient to say that

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the cited references can be combined or modified without a teaching in the prior art to suggest the desirability of the modification); (2) there must also be a reasonable expectation of success; and (3) the references as combined must collectively teach or suggest all limitations of the claims. The teaching or suggestion to combine and modify the cited art and the reasonable expectation of success must both be found in the prior art and not in Applicants' Specification. (M.P.E.P. §2143).

Before discussing the specific requirements for establishing *prima facie* obviousness, Applicants would like to highlight their claimed invention. Applicants' claimed invention is directed to a surprisingly economical and environmentally friendly process for producing sterols, wherein the process comprises two separate transesterification steps. (See, Applicants' Specification, page 2, lines 27-29). Applicants' claimed process comprises: (a) providing an oil distillation residue comprising sterol esters and partial glycerides; (b) transesterifying the partial glycerides with a lower alcohol in the presence of a basic catalyst under mild transesterification conditions to form fatty acid alkyl esters and glycerol; (c) removing excess lower alcohol, the basic catalyst, the glycerol and the fatty acid alkyl esters, to form a bottom product comprising the sterol esters; and (d) transesterifying the sterol esters at a temperature of from 90°C to 145°C and a pressure of from 2 to 10 bar for a period of from 4 to 10 hours to form free sterols.

Applicants respectfully submit that the Hunt references fail to teach or suggest each and every element of Applicants claimed invention. Moreover, neither reference contains any teaching which would motivate one of ordinary skill in the art to modify the teachings of either Hunt reference as suggested by the Examiner in order to arrive at Applicants' claimed invention.

Applicants have found that where the initial transesterification is conducted under mild conditions, such that very little free sterol is formed from the sterol esters, that the process can be conducted so as to obtain highly concentrated sterols, with less energy consumption. (See, Applicants' Specification, p. 2, line 30, through p. 3, line 13).

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Neither Hunt '252, nor Hunt '669, nor a combination of the two references, teaches a process for producing sterols wherein a first transesterification is performed under mild conditions such that very little sterol ester is converted to free sterol. Hunt '252 teaches the transesterification of the partial glycerides present in the starting material at temperatures of "between about 150°C and about 240°C and in reaction times of 10 minutes or more, e.g. about 1 to about 3 hours", under pressure. (See, Hunt '252, col. 5, lines 20-24). These conditions are not mild.

The differences between these relatively harsh transesterification conditions disclosed in the Hunt references and the "mild" transesterification conditions employed in the first transesterification according to Applicants' claimed invention are evidenced in three ways. First, the conditions disclosed in Hunt '252, as set forth above, are different than the conditions which are set forth in Applicants' Specification as being mild. Applicants' preferred "mild" conditions for the first transesterification are temperatures of from 115°C to 145°C for from 5 to 20 minutes. (See, Applicants' Specification, p. 4, lines 8-17). Second, upon reviewing Hunt '252, one can see that the second transesterification, the transesterification of the sterol esters, is conducted under the same conditions as the first transesterification, namely temperatures of "between about 150°C and about 240°C and in reaction times of 10 minutes or more, e.g. about 1 to about 3 hours", under pressure. (See, Hunt '252, col. 6, lines 24-28). Hunt '252 discloses two transesterifications performed under identical conditions. Based upon the fact that the first transesterification is conducted under the same conditions disclosed for the transesterification of the sterol esters, it is clear that some sterol ester can be transesterified during the first transesterification disclosed in Hunt '252. Accordingly, it is clear that the first transesterification disclosed in Hunt '252 is different than the mild transesterification of Applicants' claimed invention. Third, Hunt '669 specifically discloses that in the pre-esterification/transesterification portion of the process disclosed therein that, "the sterol fatty acid ester is reacted to sterol and fatty acid methyl ester." (See, Hunt '669, col. 6, lines 58-62).

The Examiner has argued that altering the transesterification parameters is routine optimization. Applicants respectfully disagree. Nothing in either Hunt reference indicates that

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lower temperatures or generally mild conditions should be used in the first transesterification, but not the second, nor is there any indication that shorter reaction times are optimum. As §§2144.05(II)(A&B) of the M.P.E.P. make clear, in order for an obviousness rejection to be based upon routine optimization of a parameter or variable, the allegedly optimizable variable must be recognized as a result-effective variable. Neither Hunt reference recognizes any advantage to be obtained by conducting the first transesterification under varying conditions, much less mild conditions such that a majority of the sterol ester present survives as the ester. Accordingly, there is no suggestion in either reference which would motivate one of ordinary skill in the art to utilize the mild conditions described by Applicants.

Finally, one of ordinary skill in the art would find no reasonable expectation of successfully increasing the yield and purity of sterols recovered via the process disclosed in the Hunt references by decreasing the reaction temperature and/or time during the first transesterification. Hunt '252 suggests carrying out the typical first transesterification for an amount of time and at temperatures such that about 90% of the fatty acids and fatty acid glycerides present are transesterified. (*See*, Hunt '252, col. 5, lines 24-29). This hardly suggests better results by shortening the reaction time.

Accordingly, as the Hunt references fail to teach or suggest each and every element of the claimed invention, fail to motivate modification of their teachings such that one of ordinary skill in the art would arrive at the claimed invention, and fail to provide one of ordinary skill in the art with a reasonable expectation of success, Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness based upon the Hunt references. Withdrawal of the rejection of claims 1-19 under §103(a) is respectfully requested.

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In view of the remarks set forth above, Applicants submit that all pending claims patentably distinguish over the prior art of record and known to Applicants, either alone or in combination. Accordingly, reconsideration, withdrawal of the rejections and a Notice of Allowance for all pending claims are respectfully requested.

Respectfully submitted,

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